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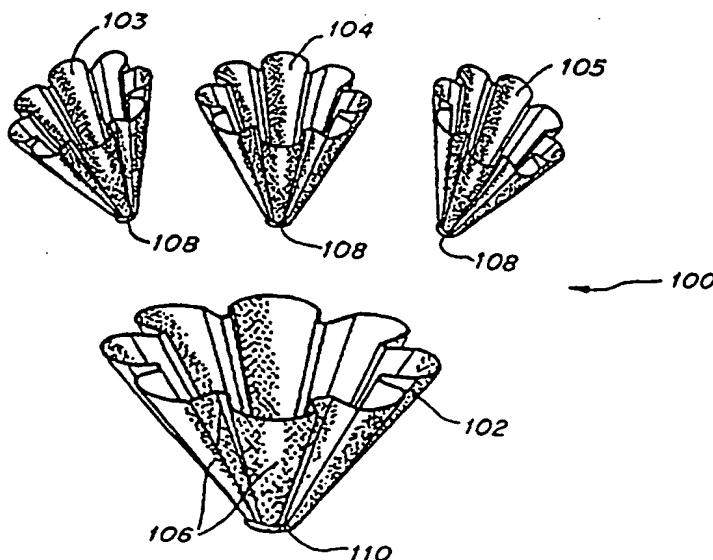
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## Published

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(54) Title: IMPROVED PROSTHESIS FOR HERNIA REPAIR AND SOFT TISSUE RECONSTRUCTION



## (57) Abstract

An implantable prosthesis for repairing or reconstructing a tissue or muscle wall defect including an outer plug and at least two inner filler plugs positioned within the outer plug that stiffen, and impart bulk to, the outer plug when the implant is inserted into the narrow confines of the tissue or muscle wall defect.

**IMPROVED PROSTHESIS FOR HERNIA REPAIR  
AND SOFT TISSUE RECONSTRUCTION**

**FIELD OF THE INVENTION**

5       The present invention relates to an improved prosthesis for hernia repair and soft tissue reconstruction.

**BACKGROUND OF THE INVENTION**

      The PerFix® Plug, available from C.R.Bard, Inc, the assignee of the present application, and described in U.S. Patent No. 5,356,432, is a pre-formed, knitted polypropylene  
10   monofilament mesh prosthetic used in the repair of direct, indirect and femoral hernias. The PerFix® plug 10, illustrated in Fig. 1, consists of a hollow, conical outer body 12, that tapers outwardly from a rounded tip 14 to an open base 16. The surface of the outer body is pleated 18, allowing the implant to conform to irregularities in the tissue or muscle wall defining the defect. An inner filler body of mesh petals 20 is provided within the outer plug and imparts bulk, for  
15   handleability, and stiffness to snugly fit the prosthetic within the tunneling defect, preventing the formation of gaps between the implant and the surrounding muscle or tissue wall which may potentially lead to recurrent herniation. The atraumatic tip of the implant is inserted into the defect until the margin of the base is flush with the opening to the defect. The implant is secured in position with interrupted sutures through the mesh margin. The PerFix® plug has achieved  
20   notable commercial success and widespread recognition from the surgical community as a significant advance in the treatment of groinal hernia defects.

      The present invention is an enhancement of the PerFix® plug, particularly indicated for use in the repair of large tissue ruptures.

25       **SUMMARY OF INVENTION**

      The present invention is a biologically compatible, implantable prosthesis for use in the repair of groinal hernia defects and in other soft tissue reconstruction. The repair and reconstructive device includes an outer plug, preferably formed of a single layer of tissue infiltratable fabric, which is compressible into a slender shape which fits within an opening in a  
30   tissue or muscle wall defect. The surface of the outer plug may be pleated to facilitate conformance of the plug to irregularities in the shape of the rupture. An inner filler body, consisting of at least two plugs also preferably formed of single layers of a tissue infiltratable fabric, is positioned within the outer plug and imparts bulk to, and stiffens, the implant when it is

compressed within the defect. Use of the inner filler plugs avoids the need to stiffen the single layer outer plug itself, reducing the likelihood that the prosthesis will kink or buckle when fitted in an irregularly shaped opening.

In one embodiment of the invention, the prosthetic includes a conical mesh outer plug  
5 having a rounded atraumatic tip, an open base and a cavity therebetween. Two or more similarly shaped, but smaller, conical filler plugs are fixedly positioned within the cavity with the tips of the mesh filler plugs being stitched to the tip of the larger outer plug. Sidewall stitches may be used to secure the inner filler plugs to the mesh outer plug, preventing the smaller plugs from riding up the sidewall of the outer plug and potentially obscuring the margin of the implant  
10 which is typically employed as a site for suturing the prosthetic to neighboring tissue. The outwardly resilient inner plugs fill the open space of the hollow outer plug, enhancing the bulkiness and stiffness of the implant when the outer conical plug is compressed upon insertion into the defect.

It is among the general objects of the invention to provide an implant for the repair of  
15 inguinal hernias and for other types of soft tissue reconstruction.

It is another object of the invention to provide a prosthesis which is particularly indicated for the treatment of large defects in muscle and tissue wall.

Other objects and features of the present invention will become apparent from the following detailed description when taken in connection with the accompanying drawings which  
20 disclose multiple embodiments of the invention. It is to be understood that the drawings are designed for the purpose of illustration only and are not intended as a definition of the limits of the invention.

### DESCRIPTION OF THE DRAWINGS

25 The foregoing and other objects and advantages of the invention will be appreciated more fully from the following drawings in which:

Fig. 1 is an illustration of the PerFix® plug disclosed in U.S. Patent No. 5,356,432;

Fig. 2 is an exploded illustration of the enhanced implantable prosthesis of the present invention; and

30 Fig. 3 is an illustration of an assembled implantable prosthesis according to the present invention.

### DESCRIPTION OF THE PREFERRED EMBODIMENTS

The implantable prosthesis 100 for repairing tissue and muscle wall defects, illustrated in Figs. 2-3, includes a flexible, hollow outer plug 102 which is compressible into a slender configuration that approximates the shape of the defect and at least two or more inner filler plugs 103-105, preferably three, which impart bulk to, and stiffen, the implant when it is confined within the tissue or muscle wall opening. The outer mesh body may be conical, as shown, and a portion or all of the surface of the outer plug may be pleated 106 to enhance the pliability and flexibility of the implant, allowing the prosthetic to conform to irregularities in the shape of the hernia without kinking or buckling. At least one, and preferably all, of the inner filler plugs may be smaller versions of the outer plug, having a conical shape, rounded tip, open base, longitudinal pleats and being radially compressible. The pleated surface of the inner plugs, and outward resilience, enhance the packing and stiffening affect of the mesh filling. The inner filler plugs may be positioned side-by-side along a transverse axis of the implant as illustrated, or may be arranged circumferentially, or in any other fashion as would provide the desired stiffness and bulkiness when the outer plug is seated within the constricting confines of the tissue or muscle wall rupture.

A relaxed and uncompressed outer plug, prior to insertion into a defect, is illustrated in Fig. 3 with the inner filler plugs arranged side-by-side so that there is at least one point of contact between the sidewalls of adjacent filler plugs and, preferably, at least one point of contact between the sidewalls of the outer plug and the inner plugs positioned thereagainst. The inner filler plugs may be partially flattened to make room for the other plugs. As shown, the plugs are pinched to such an extent that pleats on opposing sides lie in a common vertical plane. Although the inner filler plugs are illustrated as having the same size and shape, varying sizes and shapes of these components are contemplated so long as the mixture of plugs ultimately chosen enhances the packing of the outer plug. Thus, the inner plugs may have a conical, truncated conical or cylindrical shape, or other configuration, which may be partially compressed as other filler plugs are added to the outer plug cavity and which may become extensively reduced when the implantable prosthesis is placed within the tissue or muscle wall defect.

The inner filler plugs may be secured through their tips 108 to the atraumatic end 110 of the outer plug. This arrangement allows independent movement of each filler plug relative to the outer plug, and to each other, as the implant is compressed by the narrow tunneling walls of the hernia. Sidewall stitches, or other fastening mechanisms, may additionally be provided to secure

at least the outermost of the filler plugs and the outer plug. These junctions restrain the inner filler bodies from protruding beyond the base of the outer plug when the implant is compressed, preventing the margin of the outer base, used to suture or staple the implant to neighboring tissue, from becoming obscured. Providing the inner filler bodies with a predetermined height  
5 that is shorter than the outer plug also ensures sufficient clearance for fixation of the outer plug base.

The outer plug and inner filler plugs are preferably formed of knitted polypropylene monofilament mesh fabric, such as Marlex® mesh. Other biologically compatible soft tissue reconstruction or repair materials, having openings for tissue ingrowth, are contemplated  
10 including, without limitation, Prolene®, Dacron®, Teflon® (expanded PTFE) and Merselene®. Although a single layer knitted monofilament fabric is preferred, the porous prosthetic repair material may alternatively be formed of multifilament yarns and woven, braided and extruded devices are considered within the scope of the invention as are multiple layer devices. The larger  
15 outer and smaller inner filler plugs preferably are formed by hot molding a circular sheet of mesh fabric into a cone or other desired plug shape. The cone is supported in a fixture having fins which project into the mesh plug for forming the rounded pleats. The prosthetic is heated and then cooled, forming a single layer plug with the desired shape and longitudinally pleated surface. In a representative embodiment, the implantable prosthesis for hernia repair and soft  
20 tissue reconstruction includes a conical outer plug formed of Marlex® knitted monofilament polypropylene mesh fabric having a height of 1.5 inches and a round base with a diameter of 2.0 inches and three inner filler plugs, also formed of Marlex® mesh, arranged side-by-side within the outer plug, and having a height of 1.1 inches and a pre-assembled diameter of 1.5 inches. When fixed within the outer plug, the base of the partially flattened inner filler plugs has a major axis diameter of 1.75 inches and a minor axis diameter of .375 inches. A clearance of .1875  
25 inches is provided between the end of the filler plugs and the margin of the outer plug base.

The present invention therefore provides a prosthetic implant, amongst which are certain of the following advantages. The mesh device is compressible into varying shapes and sizes, allowing a single, or at most a nominal range of sizes, to be indicated for the repair of most commonly occurring inguinal defects and soft tissue reconstructions. The pleated surface allows  
30 the implant to conform to localized irregularities in the contours of the rupture. A relatively enhanced stiffening and bulking affect is provided by the filler plugs, allowing the prosthesis to be used in the repair of large defects.

It should be understood that the foregoing description of the invention is intended merely to be illustrative thereof and that other embodiments, modifications, and equivalents of the invention may be within the scope of the invention recited in the claims appended hereto.

Consequently, although the invention has been described in connection with a conical outer plug  
5 and three conical inner filler plugs, the scope of the invention includes other shapes of outer and  
filler plugs and a greater or lesser number of filler plugs. While the outer and filler plugs may  
have rounded tips and pleated surfaces, the breadth of the invention covered hereby is not so  
limited. Further, the inner filler plugs may be constructed and arranged within the outer plug  
cavity so that they do not become compressed or flattened until the prosthesis is placed within a  
10 smaller defect opening.

CLAIMS

1. An implantable prosthesis for repairing or reconstructing a tissue or muscle wall defect, comprising:

a flexible, hollow outer plug formed of a biologically compatible, implantable fabric  
5 having openings therein for tissue ingrowth, said hollow plug including a cavity therein and being compressible radially upon insertion into the defect; and

at least two inner filler plugs pre-formed to include a sidewall defining a cavity in an uncompressed configuration, and being further formed of a biologically compatible, implantable fabric having openings therein for tissue ingrowth and positioned within said outer plug cavity  
10 which impart bulk to, and stiffen, said implantable prosthesis when said outer plug is compressed radially upon insertion into the defect.

2. The implantable prosthesis recited in claim 1 wherein said outer plug is compressible into a configuration which closely approximates the shape of the defect.  
15

3. The implantable prosthesis recited in claim 1 wherein said outer plug further includes a pleated surface which is conformable to irregularities in the tissue or muscle wall defining the defect when said outer plug is compressed.

20 4. The implantable prosthesis recited in claim 1 wherein said outer plug is conical.

5. The implantable prosthesis recited in claim 1 wherein at least one of said at least two inner filler plugs is conical.

25 6. The implantable prosthesis recited in claim 1 wherein at least one of said at least two inner filler plugs includes a pleated surface in an uncompressed configuration.

7. The implantable prosthesis recited in claim 1 wherein said at least two inner filler plugs are moveable relative to one another.  
30

8. The implantable prosthesis recited in claim 1 wherein said at least two inner filler plugs are moveable relative to said outer plug.

9. The implantable prosthesis recited in claim 1 wherein said outer plug includes a sidewall and at least one of said at least two inner filler plugs is secured to said sidewall.

5 10. The implantable prosthesis recited in claim 1 wherein said at least two inner filler plugs are shaped similarly to, but are smaller versions of, said outer plug.

11. The implantable prosthesis recited in claim 1 wherein said outer plug includes a tip, said at least two inner filler plugs include a tip, and said tips of said at least two inner filler  
10 plugs are attached to said tip of said outer plug.

12. The implantable prosthesis recited in claim 1 wherein said outer plug includes a fastening margin at one end thereof, and said inner filler plugs are constructed and arranged within said outer plug cavity so as not to obscure said fastening margin when said outer plug is  
15 compressed.

13. The implantable prosthesis recited in claim 1 wherein said at least two inner filler plugs are arranged side-by-side.

20 14. The implantable prosthesis recited in claim 1 wherein said outer plug and said at least two inner filler plugs each include a tip and a sidewall and wherein there is at least one point of contact between said sidewalls of adjacent of said at least two inner filler plugs and at least one point of contact between said sidewalls of said outer plug and said at least two inner filler plugs.

25

15. The implantable prosthesis recited in claim 1 wherein said at least two inner filler plugs includes three inner filler plugs.

30 16. An implantable prosthesis for repairing or reconstructing a tissue or muscle wall defect, comprising:

a flexible conical outer plug formed of a biologically compatible, implantable fabric having openings therein for tissue ingrowth, including an atraumatically configured end, an open



base and a cavity therebetween, said conical outer plug being radially compressible upon insertion into the defect into a configuration which approximates the shape of the defect and including a pleated surface which allows said outer plug to conform to irregularities in the tissue or muscle wall defining the defect; and

5       at least two flexible conical inner filler plugs, each formed of a biologically compatible, implantable fabric having openings therein for tissue ingrowth, said at least two flexible conical inner filler plugs including a pleated surface in an uncompressed configuration and being positioned within said outer plug cavity, whereby said at least two flexible conical inner filler plugs impart bulk to, and stiffen, said implantable prosthesis when said flexible conical outer  
10   plug is compressed upon insertion into the defect.

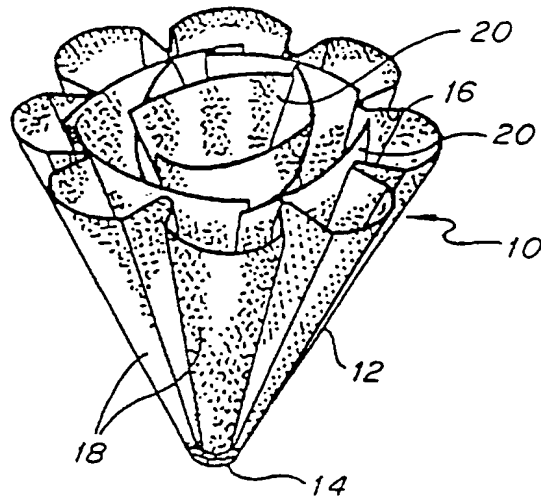
17.   The implantable prosthesis recited in claim 16 wherein said at least two inner conical filler plugs are in a partially flattened configuration prior to radial compression of said outer plug.

15       18.   The implantable prosthesis recited in claim 17 wherein said pleated surface on opposing sides of said at least two inner conical filler plugs lies in a common vertical plane prior to radial compression of said outer plug.

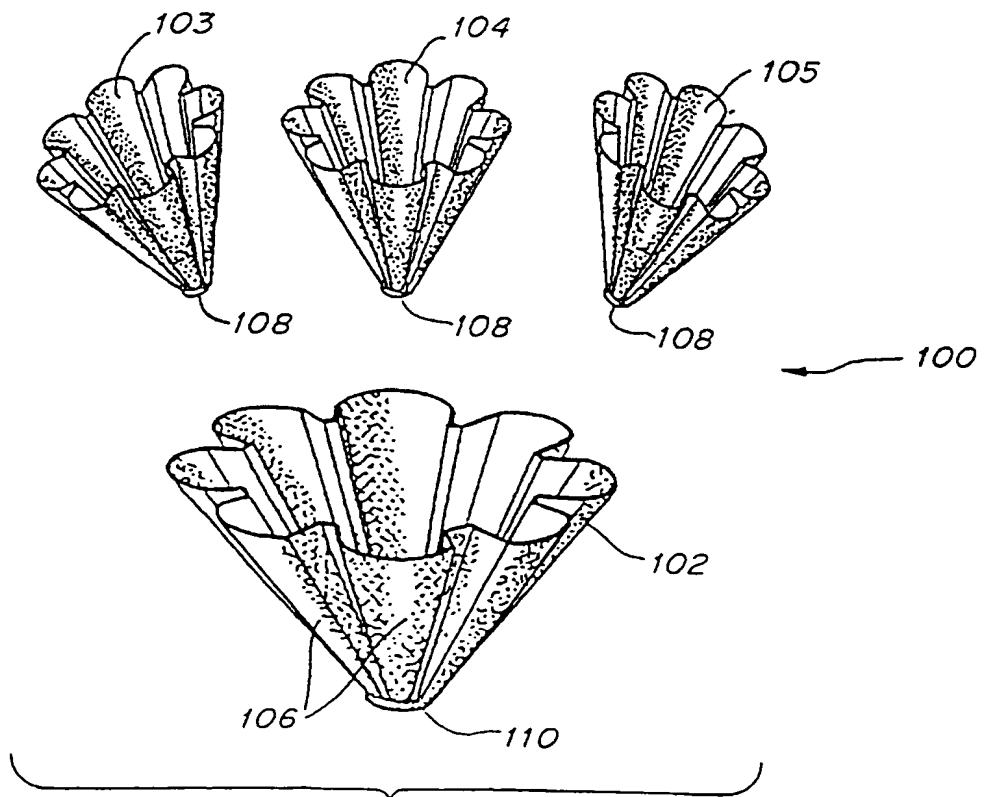
20       19.   The implantable prosthesis recited in claim 16 wherein said at least two flexible conical inner filler plugs include a tip, an open base and a cavity therebetween.

25       20.   The implantable prosthesis recited in claim 16 wherein said outer conical plug includes a margin and said at least two inner conical filler plugs are constructed and arranged within said outer plug cavity to provide clearance for said margin.

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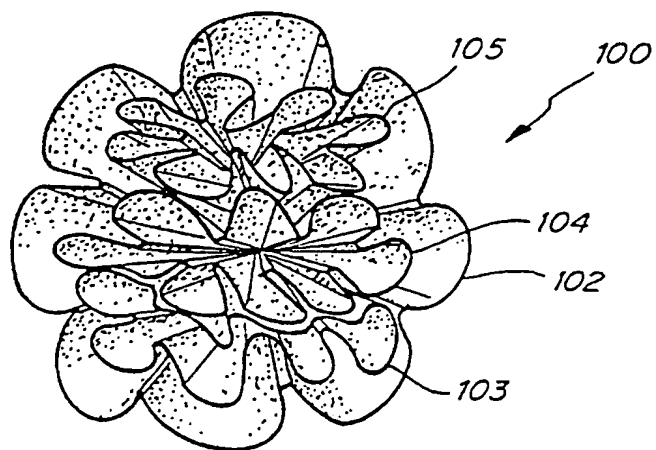
*Fig. 1*  
PRIOR ART



*Fig. 2*

SUBSTITUTE SHEET (RULE 26)

2/2



*Fig. 3*

# INTERNATIONAL SEARCH REPORT

Intern: J Application No  
PCT/US 97/09075

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 6 A61F2/00 A61B17/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP 0 614 650 A (BARD INC C R) 14 September 1994 cited in the application see column 3, line 7 - column 4, line 42; figures	1-4,11
A		9,12,15, 16,18-20
A	WO 95 27448 A (COOK WILLIAM EUROP ;KAVTELADZE ZAZA ALEXANDROVICH (RU); KORSHOK AL) 19 October 1995 see page 11, line 12 - line 22; figure 7 -----	1,5,16

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

### \* Special categories of cited documents:

- \* "A" document defining the general state of the art which is not considered to be of particular relevance
- \* "E" earlier document but published on or after the international filing date
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- \* "O" document referring to an oral disclosure, use, exhibition or other means
- \* "P" document published prior to the international filing date but later than the priority date claimed

- \* "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- \* "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- \* "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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Date of the actual completion of the international search

5 September 1997

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# INTERNATIONAL SEARCH REPORT

Information on patent family members

Intern: d Application No

PCT/US 97/09075

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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WO 9527448 A	19-10-95	AU 2255195 A	30-10-95

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